

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------------|----------------------|---------------------|------------------|
| 10/517,450 | 09/01/2005 | Marc Donath | 4614-0160PUS1 | 5584 |
| 2292 7590 02/07/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | EXAMINER | |
| | | | DANG, IAN D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | . 1647 | |
| | | | | |
| SHORTENED STATUTORY | Y PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE | |
| 31 D. | AYS | 02/07/2007 | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 02/07/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| b` | | Application No. | Applicant(s) | | |
|--|--|--|---|--|--|
| | | 10/517,450 · | DONATH, MARC | | |
| | Office Action Summary | Examiner | Art Unit | | |
| | | lan Dang | 1647 | | |
| | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | |
| WHICI - Extens after S - If NO - Failure Any re | DRTENED STATUTORY PERIOD FOR REPLY HEVER IS LONGER, FROM THE MAILING DASIONS of time may be available under the provisions of 37 CFR 1.13 (b) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing dipatent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | J. lely filed the mailing date of this communication. O (35 U.S.C. § 133). | | |
| Status | | • | | | |
| 1) 🗌 | Responsive to communication(s) filed on | : | | | |
| 2a) <u></u> □ | This action is FINAL . 2b) This action is non-final. | | | | |
| 3) 🗌 | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition | on of Claims | | | | |
| ` 4)⊠ · | Claim(s) <u>1-14</u> is/are pending in the application. | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) | Claim(s) is/are allowed. | | | | |
| | Claim(s) is/are rejected. | | | | |
| · | Claim(s) is/are objected to | | | | |
| 8)⊠ | Claim(s) <u>1-14</u> are subject to restriction and/or e | election requirement. | · | | |
| Application | on Papers | • | | | |
| 9)[☐ Т | The specification is objected to by the Examine | r. | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority u | nder 35 U.S.C. § 119 | • | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| • | | | | | |
| Attachment | (s) | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date Other: Other: | | | | | |

Art Unit: 1647

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claim(s) 1-5 and 8-12, drawn to a method of using a compound of an Interleukin receptor antagonist (IL-1Ra) for the treatment or prophylaxis of type 2 diabetes in a mammal.
- Group II, claim(s) 6-7 and 13-14, drawn to a method of using a compound of a pyrrolinidedithiocarbamate (PDTC) for the treatment or prophylaxis of type 2 diabetes in a mammal.

The examiner has interpreted the terms "use of an Interleukin 1 receptor antagonist" in claim 1 as a compound for the preparation of a medicament for the treatment or prophylaxis of type 2 diabetes in a mammal.

In addition, the examiner has interpreted the terms "the use of pyrrolinidedithiocarbamate (PDTC) in claim 6 as a compound for the preparation of a medicament for treatment or prophylaxis of type 2 diabetes in a mammal.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as

Application/Control Number: 10/517,450

Art Unit: 1647

Groups I-IV do not relate to a single general inventive concept because they lack the same or corresponding technical feature.

Claim 1 is directed to a compound of an Interleukin receptor antagonist (IL-1Ra) for the treatment or prophylaxis of type 2 diabetes in a mammal. Giannoukakis et al. (Diabetes, 1999, Volume 48, pages 1730, abstract) teach the Interleukin-1 receptor antagonist protein for the prevention and treatment of insulitis and the consequent pathogenesis of diabetes. The prior art meets the limitations disclosed in claim 1. Thus Group I lacks novelty or inventive step and does not make a contribution over the prior art. Since the first claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed invention.

Under PCR Rule 13.1, the application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on 9am to 5pm.

Application/Control Number: 10/517,450

Art Unit: 1647

Page 4

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang Patent Examiner Art Unit 1648 February 5, 2007

dget C. Dunnes

BRIDGET BUNNER